

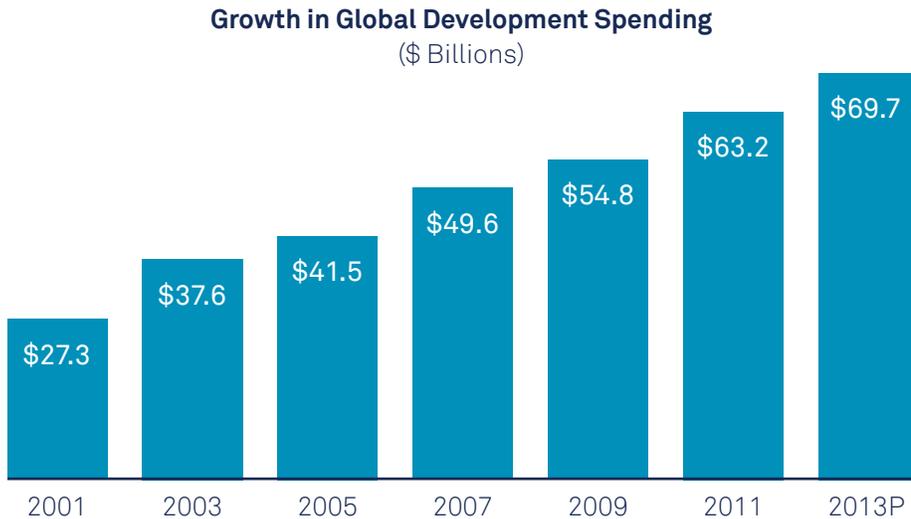
Optimizing Data and Technology in Clinical Investigator Cost Management

Delivering Quantitative Value for Clinical
Sponsors Related to the Cost of Drug
Development

Clinical Investigator Cost Management

Year over year, drug development costs have skyrocketed and are expected to break \$70 billion in 2014—a 155 percent increase since 2001 (Figure 1). With the cost of development increasing, coupled with a slim 20 percent probability of drug success in Phase-I, II and III studies¹, sponsors increasingly find that they need to manage program costs more effectively to ensure that they are spending efficiently.

Figure 1



Source: Tufts CSDD, PhRMA.org

Medidata is uniquely qualified within the healthcare industry to provide clinical research sponsors with the data and technology to identify and address their drug development challenges. Combining Medidata’s rich data assets, technology and tools with domain expertise, we deliver quantitative value that assists sponsors with effective management of clinical investigator site costs. This unique value can be categorized into the following areas:

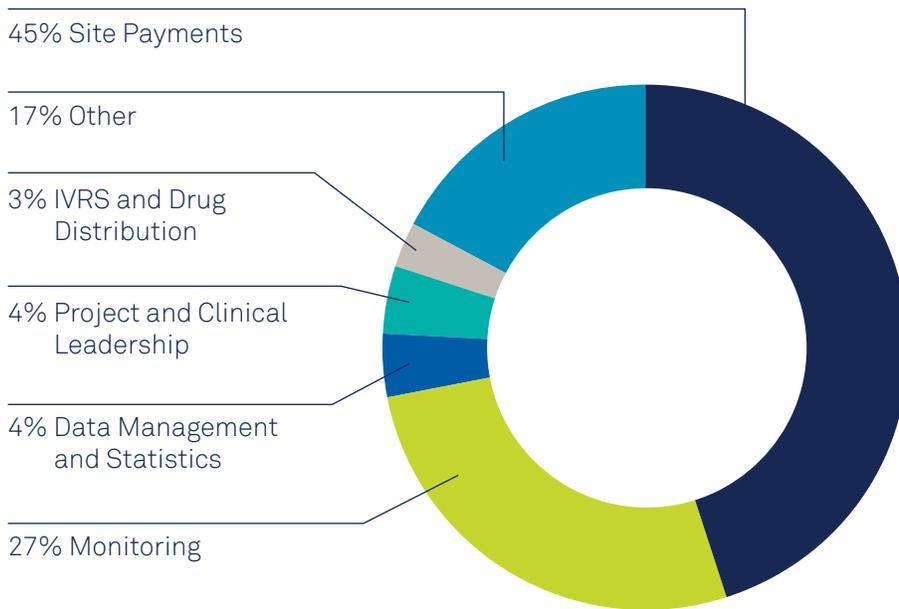
- I. Cost containment & reduction
- II. Process improvement
- III. Fair-market-value (FMV) compliance & regulatory reporting facilitation

I. Cost Containment & Reduction

Sponsors clearly recognize the need to contain or reduce drug development costs. Although nearly 50 percent of a sponsor’s annual development costs are associated with investigator site fees (Figure 2), identifying areas for cost mitigation may be difficult, especially with increased pressure to get drugs to market faster. Medidata works with sponsors on the interpretation and practical application of industry benchmark cost data. In addition, Medidata helps sponsors negotiate FMV site costs in accordance with best practices and compliance.

Figure 2

Costs Breakdown for a Large, Global Clinical Trial
(14,000 patients, 300 sites)¹



¹IOM (Institute of Medicine). 2010. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington, DC: The National Academies Press.

The following business cases provide a comparative analysis of negotiated site costs between sponsors that used data sources other than Medidata PICAS® benchmark data for determining site costs. The analysis, conducted by Medidata’s data quality and analytics team, quantifies the value sponsors realize through our partnerships and reinforces how Medidata Grants Manager®/PICAS can help budgeters make better, more informed decisions.

NB: Sponsor names have been changed for confidentiality purposes.

Case Study One: Avoiding Overpayment*

Medidata's Data Quality and Analytics team compared three data sources to help Sponsor Beta understand how their benchmarked negotiated site fees may vary depending on which data source is used.

- Data Source One—Sponsor Beta: Over 500 grants negotiated by Sponsor Beta within the previous 24 months. Sponsor Beta's grants were negotiated using industry available, non-Medidata cost benchmark data.
- Data Source Two—Large Pharma: Median costs negotiated by three large pharma sponsors of similar size and global reach utilizing Grants Manager/PICAS exclusively to determine investigator site costs.
- Data Source Three—Industry: Median costs negotiated by over 150 sponsors utilizing Grants Manager/PICAS exclusively to determine investigator site costs.

Even a two-five percent reduction in site fees from Sponsor Beta's current levels represents a potential \$11.7M in annual savings.

Findings

Sponsor Beta's annual investigator site costs are projected to be nearly \$1.305B. Even a two percent reduction in site fees from Sponsor Beta's current levels represents a potential annual savings of nearly \$12M. Sponsor Beta concluded they overspent up to 17 percent of their total spend based on the information available in Figure 3 and Figure 4.

Figure 3: The yellow highlighted costs indicate overpayment by Sponsor Beta, sometimes by as much as 100 percent. The circled costs also indicate overpayment, but may be justifiable given the type of procedure and the complexity of the studies designed by Sponsor Beta.

Short Description	Sponsor Beta	Large Pharma	All of Industry
Informed Consent Process	\$ 85.00	\$ 80.00	\$ 95.00
Patient Reimbursement	\$ 1,062.29	\$ 477.23	\$ 509.63
Adverse Events Assessment	\$ 35.00	\$ 30.00	\$ 30.00
Physician's Fees without Exam Costs per visit	\$ 146.32	\$ 128.00	\$ 126.00
Review Concomitant Medications	\$ 39.00	\$ 25.00	\$ 25.00
ECG w/ Interpret. & Report	\$ 113.00	\$ 100.00	\$ 100.00
Spec Handling (simple)	\$ 32.00	\$ 15.00	\$ 23.00
Salaries: Coord, Nurse, Admin, Tech per visit	\$ 132.50	\$ 110.00	\$ 121.47
Follow-Up Visit w Phys/Vitals	\$ 150.00	\$ 125.00	\$ 150.00
Urine Pregnancy Test, Qualitative	\$ 25.98	\$ 20.00	\$ 20.00
Pharmacy Fee; Incl. Fixed & Disp.	\$ 416.00	\$ 253.00	\$ 270.00
Pharm Disp p/visit (simple) per visit	\$ 32.00	\$ 25.00	\$ 28.00
Init Phys Exam & Vitals Only	\$ 150.00	\$ 160.00	\$ 165.00
Initial History Only	\$ 97.00	\$ 100.00	\$ 100.00
Brief Visit w/ Vitals	\$ 42.00	\$ 40.00	\$ 38.47
Medical Outcomes SF-36; MOS SF-36	\$ 29.00	\$ 23.65	\$ 20.00
Study Coordinator Fee Per Visit	\$ 132.53	\$ 51.28	\$ 103.88
EuroQoL; EQ-5D	\$ 25.00	\$ 25.00	\$ 25.00
Living W Chronic Hepatitis C Q, QOL	\$ 32.00		
Patient Daily Reimbursement	\$ 67.00	\$ 40.00	\$ 46.00
Urine Collection, Up to 24 Hours	\$ 17.00	\$ 15.00	\$ 15.00
Venipuncture	\$ 29.00	\$ 27.00	\$ 35.00
Pharmacy Dispensing per Patient	\$ 240.00	\$ 225.00	\$ 225.00
TSQM	\$ 38.00	\$ 25.00	\$ 20.00
Simple Telephone Consult/Visit	\$ 41.00	\$ 50.00	\$ 47.00
Serum Pregnancy Test, Quantitative	\$ 44.00	\$ 25.00	\$ 28.00
Inclusion/Exclusion Criteria	\$ 57.00	\$ 33.79	\$ 50.00
Tuberculosis Intradermal Skin Test	\$ 35.00	\$ 50.00	\$ 50.00

Figure 4: Sponsor Beta paid for the line items listed below as discrete items. The industry best practice for budget development is to include these within a salary. Because Sponsor Beta also paid higher salaries than the industry (as illustrated by the circled salaries, fees and exams in Figure 3), they effectively paid twice for each line item.

Line Item Description
Compliance Rating Scale
Dementia Quality of Life
Skin Itching Score
Extent of Disease in Tissue
Psychiatric Questionnaire
Patient Alcoholism Questionnaire
Quality of Life Patient/Family
Living with Chronic Hepatitis
Treatment Satisfaction Survey

Sponsor Omega significantly reduced their negotiated cost per patient (CPP) when using Grants Manager’s PICAS benchmark data by leveraging the costs most often-paid in the industry.

Case Study Two: Benchmarking Against Your Peers*

Medidata’s Data Quality and Analytics team compared three data sources to help Sponsor Omega understand the change in costs after adopting Grants Manager.

- Data Source One—Sponsor Omega: Grants negotiated by Sponsor Omega within the previous 24 months. Sponsor Omega’s grants were negotiated using industry available, non-Medidata cost benchmark data.
- Data Source Two—Sponsor Omega: Sponsor Omega’s negotiated costs after adoption of Grants Manager/PICAS.
- Data Source 3—Industry: Median costs negotiated by over 150 sponsors that utilize Grants Manager/PICAS exclusively to determine investigator site costs.

Findings

Sponsor Omega significantly reduced their negotiated cost per patient (CPP) when using Grants Manager’s PICAS benchmark data by leveraging the costs most often-paid in the industry.

Figure 5: Sponsor Omega's CPP in all therapeutic areas (TAs) and in their speciality therapeutic area before and after Grants Manager/PICAS adoption.

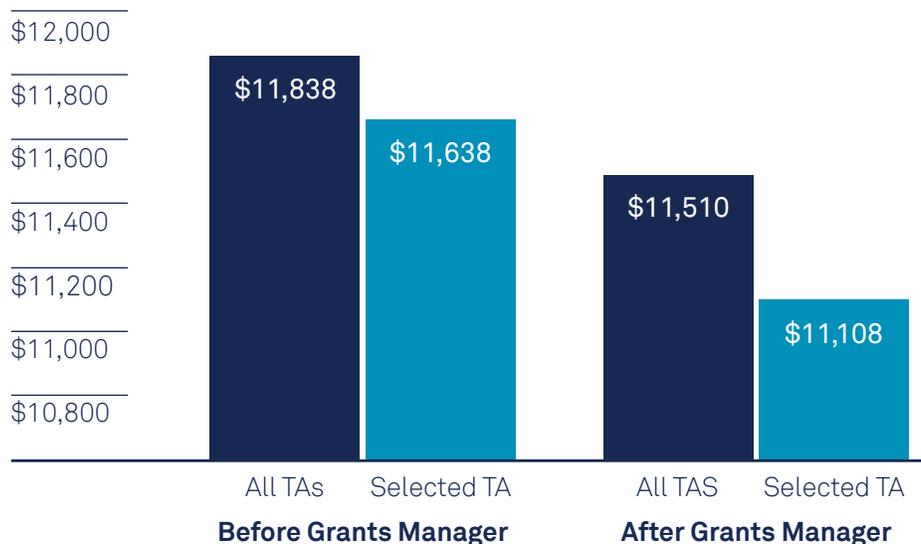
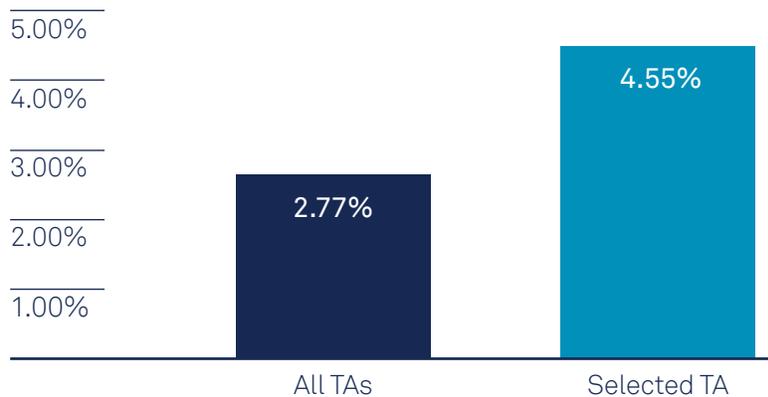


Figure 6: Sponsor Omega successfully lowered site costs by 2.76-4.55 percent in 18 to 24 months by employing true industry benchmark data in Grants Manager during the site budgeting stage, yielding a \$20M reduction in its end-negotiated site costs.



*The findings from both Case Studies conclude that not all benchmark cost data sources are created equal. The use of one benchmark data source versus another data source at the time of site budget development can have significant impact on a sponsor's end negotiated site costs and total clinical research costs.

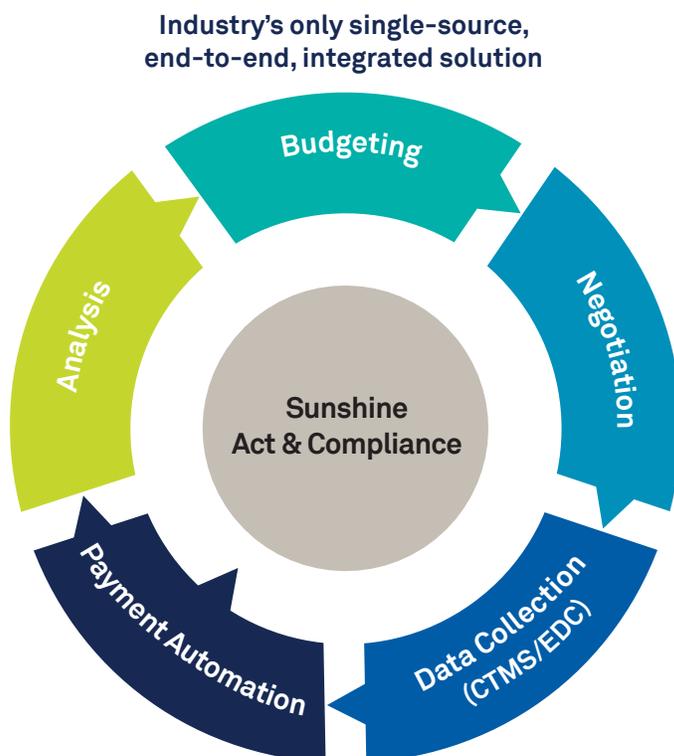
II. Process Improvement

Medidata provides the industry with the only single-source, end-to-end solution for clinical investigator cost management. Multiple, unified modules make up the Budget-to-Payment solution, offering flexibility for specific business needs. When combined with Medidata Payments, Grants Manager optimizes the site budgeting workflow, from site budgeting to payment and Sunshine Act reporting.

Medidata Budget-to-Payment Modules

- Grants Manager Planning: detailed study budget development and high-level study forecasting
- Grants Manager Contracting: online site negotiations with detailed audit history supporting FMV
- Medidata Payments: site payments administration
- Grants Manager Analysis: customer-specific database of historic negotiated costs per site

Figure 7



Optimized Budget-to-Payment Process Workflow

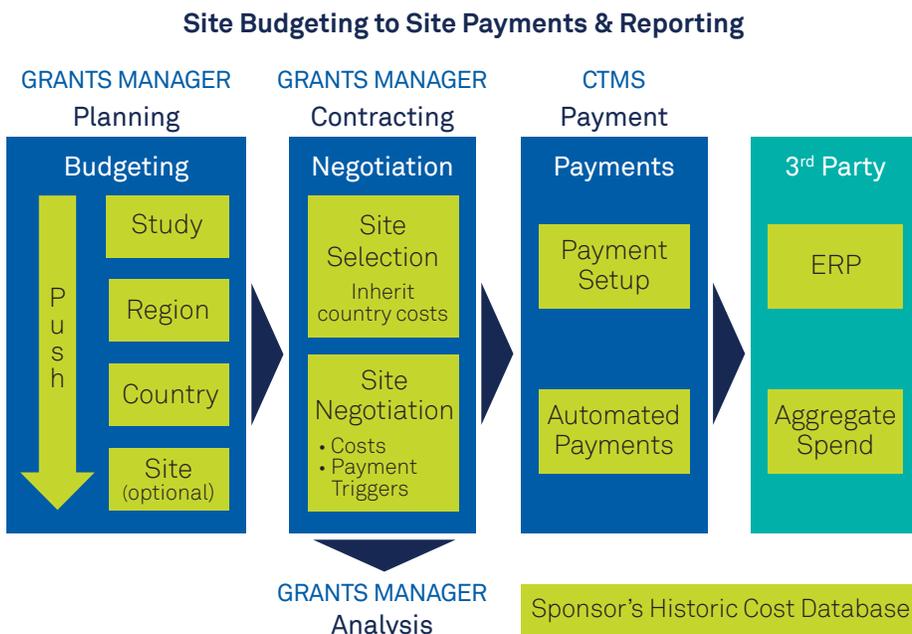
Sponsors and investigator sites report that site contract negotiations are the number one cause of delay in study start-up. The Budget-to-Payment workflow supported by Medidata’s data assets and integrated technology is designed to ensure correlation between benchmark site budget values, contracted values and payment values to produce a closed-loop process for clinical investigator cost management and compliance risk mitigation.

From a finalized master budget generated from Grants Manager Planning, sponsors open the site budget in Grants Manager Contracting and negotiate electronically with sites to reach budget agreement. Integration with Medidata Payments allows triggers to flow from Medidata Rave® and other EDC solutions to automate site payments through the sponsor’s or CRO’s accounts payable system.

This seamless workflow not only helps to expedite site negotiations and payments, potentially reducing full-time equivalent (FTE) by 25 percent, but also assists sponsors with FMV compliance and Sunshine Act reporting requirements through detailed audit histories of all negotiations and payments.

Final negotiated site budgets from Grants Manager Contracting appear in Grants Manager Analysis, providing a central repository of coded historic costs by site, TA, phase and time. Grants Manager Analysis also allows the sponsor or CRO to quickly ascertain historic site agreement costs to enhance future negotiations with repeating sites and supports internal and external audits.

Figure 8



III. FMV Compliance & Regulatory Reporting Facilitation

Although it is difficult to measure quantitative value for ensuring FMV payments to sites, industry sponsors are responsible for due diligence on payments to meet regulatory requirements. The closed-loop process described in Medidata's Budget-to-Payment workflow delivers a system of checkpoints to mitigate risk of non-compliance.

In addition, the use of actual industry negotiated benchmark data for determining site fees is an accepted best practice. As a result, the PICAS database that underpins Grants Manager has been employed to validate FMV sponsor payments in Office of Inspector General Deferred Prosecution Agreements.

Data Quality at the Core

Grants Manager accesses Medidata's proprietary, industry-recognized benchmark cost database, PICAS. Unlike other benchmark cost data sources, PICAS data is comprised from purely negotiated costs between sponsors and investigator sites, ensuring defensibility related to FMV. Medidata's standard operating procedures for data quality prevent non-negotiated data (including planning budgets, survey data, price lists, etc.) from entering the PICAS database, as this data may impact the accuracy of the benchmark costs generated for study budgets.

Other Unique Data Available in Grants Manager/PICAS

- Protocol Complexity/Site-Work-Effort Metric: Provides a measure of effort in a clinical trial that allows budgeters to fine-tune payments for site work based on complexity benchmarks.
- Procedure Frequency Indicators: Guides non-clinicians in the proper selection of procedures by providing the percent of times a procedure occurs in other protocols of the same phase and indication.
- Site-Specific Costs: Facilitates efficient future negotiations by providing actual cost history for over 32,000 global sites.
- Country-Specific Public Health Care Costs: Allows budget developers to reference public health care rates that may be required in certain geographies.

The PICAS Database

PICAS contains industry-wide negotiated investigator grants and contracts, covering all therapeutic areas, across all phases and all geographies.

PICAS Data Assets

- 30,000 industry protocol library
- All Phases, 15 TAs, >1400 Indications
- 300,000 negotiated investigator agreements
- Millions of industry benchmark cost data points
- Global data representing 95 countries & country regions
- 150 sponsors contribute
- Audited for confidence

Clinical Investigator Cost Management Value Summary

I. Cost Containment/Reduction

Case Study One: Avoiding Overpayment

Sponsor Beta's annual investigator site costs are projected to be nearly \$1.305B. After review of Medidata's analysis, Sponsor Beta estimated that they are spending between 11-17 percent over the industry median benchmark levels. Just a two percent reduction in site fees from Sponsor Beta's current levels represents a potential \$11.7M annually that can be directed to other clinical development opportunities.

Case Study Two: Benchmarking Against Your Peers

Sponsor Omega has experienced a 2.76-4.55 percent reduction in CPP since adopting Grants Manager/PICAS over an alternative data source for benchmarking site fees. Assuming ~8,000 patients per year in their specialty TA studies alone, Sponsor Omega realized a reduction of more than \$20M in site-per-patient costs annually.

II. Process Improvement

Sponsors and investigator sites report that site contract negotiations are the number one cause of delay in study start-up.

In a site survey conducted by Medidata, 70 percent of sites indicated that using Grants Manager Contracting saved them significant time in the negotiation process versus traditional methods such as email, phone calls, budget spreadsheet exchange and edits.² Further, Medidata sponsor clients estimate a 25 percent time reduction in the negotiation process overall.

A sponsor with a staff of 10 FTE budget negotiators at a fully loaded cost of \$125,000 per FTE yields a cost reduction of over \$300,000 annually.

This quantitative value, combined with overall process efficiency, transparency in negotiations, site satisfaction and FMV compliance yields additional value for sponsors. We estimate that in budget development through contract negotiation phases of clinical site cost management, a sponsor will realize a total value in excess of \$500,000 annually.

III. FMV Compliance & Regulatory Reporting Facilitation

Industry sponsors are tasked with conducting due diligence on payments to meet regulatory requirements even though it is difficult to measure a quantitative value on ensuring FMV payments to physicians. The use of true benchmark data in determining site fees is an industry-accepted best practice, and the PICAS database has been employed to validate sponsor payments as representing FMV in Office of Inspector General Deferred Prosecution Agreements.

The closed loop process described in Medidata's Budget-to-Payment process delivers a solution that provides checkpoints, from planned budgeted values to contractually agreed values to paid values, mitigating risk of non-compliance. By harnessing the power of PICAS—the single source of truth for determining site budgets—along with the technology in Grants Manager and Medidata Payments, sponsors can realize positive results in clinical investigator management: the planning, negotiating and managing of clinical site costs.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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Endnotes

1. PhRma Industry Profile 2013 (<http://www.phrma.org/industryprofile2013>).
2. Medidata Grants Manager Contracting Site Survey Report, July 24, 2014; N=130